## AMENDMENTS TO THE DRAWINGS

Applicant submits herewith replacement drawing sheets for FIGS. 23-26. The replacement sheets are located in the Appendix following page 15. No new matter is added by way of the replacement sheets, which merely present FIGS. 23-26 in a cleaner format, and with handwriting replaced by typeface.

## REMARKS

This Amendment is responsive to the Office Action dated April 5, 2007. Applicant has amended claims 10, 11, 65 and 66. Claims 68-70 have been added. Claims 10-16 and 55-70 are pending.

### Objection to the Drawings

The Office Action objected to the drawings as including numbers and lines that were not uniformly thick and well defined, clean, durable and black, as specified by 37 C.F.R. § 1.84(i). Submitted with this Amendment are replacement drawing sheets for FIGS. 23-26, which Applicant believes overcome the objection to the drawings. The replacement drawing sheets present FIGS. 23-26 in a cleaner format, and with handwriting that was present in FIGS. 23-26 as originally filed replaced by typeface. Applicant respectfully requests that the objection to the drawings be withdrawn in view of these replacement drawing sheets.

### Allowable Subject Matter

In the Office Action, the Examiner indicated that claims 56-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant appreciates the indication of the Examiner and reserves the right rewrite claims 56-58 in independent form at a later time.

### Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 10, 11, 14-16, 55, 62 and 63 under 35 U.S.C. § 102(e) as being anticipated by US 6,409,674 to Brockway et al. (Brockway). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Brockway et al. fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

As amended, independent claim 1 requires a housing having a tissue attachment surface and a securing structure which allows the tissue attachment surface to be brought into contact

with tissue at a preselected attachment site when in a retracted position, and is movable to an extended position in which it extends through tissue in contact with the attachment surface. Claim 1 also requires at least one physiological parameter detector carried by the housing. Claim 1 has been amended for clarity, i.e., for reasons unrelated to patentability. Brockway fails to teach or suggest each element of amended independent claim 1.

Brockway is directed to an implantable sensor device that is, for example, implanted in a chamber of the heart to monitor blood pressure within the chamber. The implantable sensor device may be secured in the heart wall to prevent the device from dislodging and entering the blood stream. However, Brockway fails to disclose a securing structure which allows a tissue attachment surface to be brought into contact with tissue at a preselected attachment site when in a retracted position, and movable to an extended position in which it extends through tissue in contact with the attachment surface.

The Office Action indicated that the stabilizer 312D described by Brockway meets the requirement in claim 10 of a movable securing structure. Brockway indicates that "stabilizer 312D... [is] made of a flexible, spring-like, or deformable material or a "memory metal."[1] "As a result of this deformation or expansion, stabilizer 312D tends to hold device 105 within the body cavity in which it is implanted."[2] However, Brockway does not teach, or even suggest, that stabilizer 312D is movable to extend through tissue, as required by claim 10.

Brockway teaches that other structures extend through tissue, rather than stabilizer 312D. In particular, Brockway describes that housing 300 may have a "sharpened end... so that housing 300 can be advanced into the heart wall."[3] However, the sharpened end is not movable, and therefore is not a movable from a retracted position to extend through tissue, as required by independent claim 10.

Dependent claims 11, 14-16, 55, 62 and 63 are allowable for at least the reasons set forth above with respect to independent claim 10, from which they depend. In addition, claims 11, 14-16, 55, 62 and 63 recite additional features that are not disclosed or suggested by Brockway. For

[1] Brockway, Col. 8, ll. 48-49.
[2] Brockway, Col. 8, ll. 53-55.
[3] Brockway, Col. 13, ll. 44-45.

example, Brockway fails to teach or suggest that the housing comprises a concavity such that the tissue attachment surface is on a surface within the concavity, as required by claim 11.

In rejecting claim 11, the Office Action pointed to stabilizer 312D of FIG. 3D, and stated that "[i]t can be seen in the figure the barbs are attached to the housing in such a way that there is a concavity where the barbs attach to the tissue."[4] First, Brockway does not describe stabilizer 312D as barbs or having barbs. Second, it is unclear to Applicant how tissue contacts the tissue attachment surface within the concavity formed by stabilizer 312D. Stabilizer 312D moves outward against the adjacent tissue, as shown in FIG. 3D. This movement provides force "to hold device 105 within the body cavity in which it is implanted."[5] However, Brockway never suggests that tissue contacts any surface within the concavity. Therefore, Brockway fails to suggest that the housing comprises a concavity such that the tissue attachment surface is on a surface within the concavity.

Brockway fails to disclose each and every limitation set forth in claims 10, 11, 14-16, 55, 62 and 63. For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 10, 11, 14-16, 55, 62 and 63 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

**Claim Rejections Under 35 U.S.C. § 103**

The Office Action rejected, under 35 U.S.C. 103(a):

1. claim 12 as being unpatentable over Brockway in view of US 4,638,045 to Kohn et al. (Kohn);
2. claim 13 as being unpatentable over Brockway in view of US 6,190,353 to Makower et al. (Makower);
3. claim 61 as being unpatentable over Brockway in view of Kohn, and further in view of US 4,981,470 to Bombeck, IV (Bombeck);
4. claim 64 as being unpatentable over Brockway in view of Bombeck;
5. claims 65 and 66 as being unpatentable over Brockway in view of Makower;

[4] Office Action, Page 4.
[5] Brockway, Col. 8, ll. 54-55.

6. claim 67 as being unpatentable over Brockway in view of Makower, and further in view of Kohn; and
7. claims 59 and 60 as being unpatentable over Brockway.

Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

***Claims 12, 13, 59-61 and 64***

Dependent claims 12, 13, 59-61 and 64 are allowable for at least the reasons set forth above with respect to independent claim 10, from which they depend. In addition, claims 12, 13, 59-61 and 64 recite additional limitations that are not disclosed or suggested by the applied references.

Claim 12 requires that the securing structure comprises a bioabsorbable material. In rejecting claim 12, the Office Action recognized that Brockway fails to teach a monitoring device wherein the securing structure comprises a bioabsorbable material. However, the Examiner pointed to Kohn as teaching a bioabsorbable material and specifically the ability of sensors to be manufactured from the material. Therefore, the Office Action reasoned that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway to include a bioabsorbable material similar to that of Kohn in order for the monitoring device to decompose harmlessly within a known period of time.

Applicant disagrees with this analysis for several reasons. First, the analysis suggests that a person of ordinary skill would have considered it obvious to modify Brockway such that the entire monitoring device decompose harmlessly, i.e., to modify Brockway such that the entire device be made of the bioabsorbable material. In view of Brockway's teaching that the monitoring device includes circuitry and the like (e.g., FIG. 3A and associated text), such a modification would make no sense to a person of ordinary skill in the art.

Furthermore, for purposes of clarification, claim 12 requires that the securing structure, not the entire monitoring device, is bioabsorbable. The teachings of Brockway and Kohn would not have made it obvious to a person of ordinary skill in the art to modify the Brockway device to

include a securing structure made of a bioabsorbable material, because such a modification would cause harm to the patient, not decompose harmlessly as suggested in the Office Action. The only embodiment of the Brockway device described in any detail, is a device designed to measure pressure within a chamber of the heart, as shown in the figures such as FIG. 5 and FIG. 7 and described throughout the Brockway disclosure. A person of ordinary skill would have understood that if a device implanted within a chamber of the heart is allowed to be released from the heart wall and into the blood stream, blood flow to at least some tissue of the patient will be impaired resulting in tissue death, or worse, patient death. For this reason, someone of ordinary skill in the art would not have considered modification of the Brockway device to include a bioabsorbable securing structure to be obvious.

As another example, claim 13 requires a lumen in communication with the concavity, for connection to a vacuum to draw tissue into the concavity. The Office Action recognized that Brockway fails to teach a monitoring device comprising a lumen in communication with the concavity for connection to a vacuum to draw tissue into the concavity. However, the Office Action pointed to Makower as teaching the user of a vacuum to draw tissue into a lumen. On this basis, the Office Action reasoned that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway to include a vacuum device similar to that of Makower in order to draw the tissue into the concavity.

Applicant disagrees with this analysis for a number of reasons. First, a person of ordinary skill in the art would have seen no purpose for the proposed modification of the Brockway device. Second, the modification of the Brockway device suggested by the Office Action would not be functional.

The Brockway device, as discussed above, includes housing 300 with stabilizer 312D attached to the housing of device 105. As disclosed by Brockway, "stabilizer 312D ... [is] made of a flexible, spring-like, or deformable material or a "memory metal."[6] "As a result of this deformation or expansion, stabilizer 312D tends to hold device 105 within the body cavity in which it is implanted."[7] The expanded stabilizer 312D provides sufficient force to anchor device 105 within the body cavity. Thus it is unclear why a person of ordinary skill in the art would

[6] Brockway, Col. 8, ll. 48-49.
[7] Brockway, Col. 8, ll. 53-55.

have seen any reason or purpose for drawing tissue into any concavity formed by the expanded stabilizer. Such tissue would not appear to be retained by the expanded stabilizer, and would in any event not seem to improve the fixation of the device.

In addition, a person of ordinary skill would likely have considered modifying the Brockway device with elements of Makower, as proposed in the Office Action, to result in a non-functional combination. As mentioned above with regard to the Brockway device, "stabilizer 312D... [is] made of a flexible, spring-like, or deformable material or a "memory metal."[8] The concavity formed by stabilizer 312D is therefore non-rigid. Thus, a person of ordinary skill in the art would have recognized that applying a vacuum to the concavity via a lumen, as suggested by Makower, may cause the concavity to collapse. In this manner, the vacuum may cause stabilizer 312D to collapse against housing 300 which may allow device 105 to break free from the heart wall. In other words, application of vacuum pressure to the concavity would prevent it from performing its intended function of retaining the Brockway device. Therefore, Brockway in view of Makower fails to suggest a lumen in communication with the concavity, for connection to a vacuum to draw tissue into the concavity.

Claims 59 and 60 require a window that permits visualization of the interior of the concavity through the housing, and that the window comprises a transparent wall of the housing, respectively. The Office Action recognized that Brockway fails to disclose these elements. However, the Office Action argued that these elements would have been an obvious matter of design choice because the Applicant has not disclosed that providing the elements provides an advantage or is used for a particular purpose or solves a stated problem.

Applicant submits that the Office Action is relying upon an improper basis for rejecting claims 59 and 60. An obviousness rejection must rely upon evidence within prior art of record that suggests the elements of the claimed invention. Design choice is an improper basis for an obviousness rejection as it not based upon evidence from the prior art. Neither Brockway, nor any other prior art of record, provides any teaching that would have suggested modification of the Brockway device to include a window that permits visualization of the interior of the concavity through the housing, or that the window comprises a transparent wall of the housing.

[8] Brockway, Col. 8, ll. 48-49.

The Office Action was incorrect in stating that Applicant has not disclosed that providing the elements provides an advantage. Applicant submits that advantages of and purposes for the window in the housing is provided within the Specification. For example, the Specification recites:

> "Preferably, the shell 120 is provided with at least a window zone or viewing area 166 to permit endoscopic visualization of the attachment cavity 124. This enables the clinician to view the tissue drawn into the attachment cavity 124, and visually assess the point at which a sufficient amount of tissue has been drawn into attachment cavity 124 to provide an adequate engagement between the pin 164 and the tissue to secure the probe 18 to the attachment site. Window 166 may be a separate structure, such as a plastic or glass wall which is transparent to visible light."[9]

The Specification discloses the purpose of the elements of claims 59 and 60 in one example embodiment, and Applicant reserves the right to respond to any prior art that may be cited in subsequent Office Actions.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 12, 13, 59-61 and 64 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

***Claims 65-67***

Claim 65 has been amended for purposes of clarity, unrelated to patentability. Similar to claim 13, discussed above, independent claim 65 requires a housing comprising a concavity such that a tissue attachment surface is on a surface within the concavity, a securing structure, a lumen in communication with the concavity for connection to a vacuum to draw tissue into the concavity to engage the securing structure, and at least one physiological parameter detector carried by the housing. For the reasons discussed above with respect to claim 13, Brockway and Makower would not have made the requirements of claim 65 obvious to a person of ordinary skill in the art.

[9] Specification, Paragraph [0096].

The Office Action was incorrect in stating that Applicant has not disclosed that providing the elements provides an advantage. Applicant submits that advantages of and purposes for the window in the housing is provided within the Specification. For example, the Specification recites:

> "Preferably, the shell 120 is provided with at least a window zone or viewing area 166 to permit endoscopic visualization of the attachment cavity 124. This enables the clinician to view the tissue drawn into the attachment cavity 124, and visually assess the point at which a sufficient amount of tissue has been drawn into attachment cavity 124 to provide an adequate engagement between the pin 164 and the tissue to secure the probe 18 to the attachment site. Window 166 may be a separate structure, such as a plastic or glass wall which is transparent to visible light."[9]

The Specification discloses the purpose of the elements of claims 59 and 60 in one example embodiment, and Applicant reserves the right to respond to any prior art that may be cited in subsequent Office Actions.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 12, 13, 59-61 and 64 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

***Claims 65-67***

Claim 65 has been amended for purposes of clarity, unrelated to patentability. Similar to claim 13, discussed above, independent claim 65 requires a housing comprising a concavity such that a tissue attachment surface is on a surface within the concavity, a securing structure, a lumen in communication with the concavity for connection to a vacuum to draw tissue into the concavity to engage the securing structure, and at least one physiological parameter detector carried by the housing. For the reasons discussed above with respect to claim 13, Brockway and Makower would not have made the requirements of claim 65 obvious to a person of ordinary skill in the art.

In addition, Brockway fails to teach or suggest a concavity wherein a tissue attachment surface is on a surface within the concavity. The Brockway device does not disclose or suggest

In addition, Brockway fails to teach or suggest a concavity wherein a tissue attachment surface is on a surface within the concavity. The Brockway device does not disclose or suggest tissue contacting the surface within any concavity formed by stabilizer 312D. Stabilizer 312D moves outward against the adjacent tissue, as shown in FIG. 3D. This movement provides force "to hold device 105 within the body cavity in which it is implanted."[10] However, Brockway never suggests that tissue contacts any surface within the concavity. Therefore, Brockway fails to suggest that the housing comprises a concavity wherein the tissue attachment surface is on a surface within the concavity.

Dependent claims 66 and 67 are allowable for at least the reasons set forth above with respect to independent claim 65, from which they depend. In addition, claims 66 and 67 recite other limitations that are not disclosed or suggested by the applied references. For example, Brockway in view of Makower fails to suggest that the securing structure comprises a pin that allows the tissue attachment surface to be brought into contact with tissue when in a retracted position, and is movable to an extended position in which it extends through the tissue in contact with the attachment surface, as required by claim 66. As discussed above with reference to claim 10, Brockway does not teach, or even suggest, that stabilizer 312D is movable to extend through tissue, as required by claim 66.

Furthermore, claim 67 requires that the securing structure comprises a bioabsorbable material. For the reasons discussed above with regard to claim 12, there is no motivation within Brockway or any other prior art of record to modify the Brockway device in order to duplicate the elements of claim 67.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 65-67 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

[10] Brockway et al., Col. 8, ll. 54-55.

**New Claims**

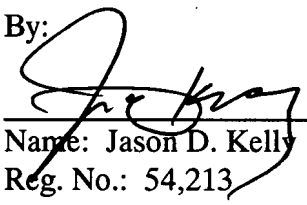
Applicant has added claims 68-70 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. Claims 68-70 include substantially similar subject matter as claims 56-58. No new matter has been added by the new claims.

## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

July 5, 2007

By: 

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